

Professional

LipidPlus®

Blood Glucose Test Strip

IMPORTANT: Please read this information and your LipidPlus® Professional Operation Manual before using the LipidPlus® Professional Glucose Test Strips. Customer Service is available Monday through Friday from 7:30AM to 5:00PM Pacific Time.

INTENDED USE

The LipidPlus® Professional Lipid Profile and Glucose Measuring System is intended for multiple patient use in professional health care settings and for testing outside the body (in vitro diagnostic use only). The LipidPlus® Professional Lipid Profile and Glucose Measuring System which consists of meter and test strips, measures total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglycerides (TG), and glucose in capillary whole blood. The LipidPlus® Professional Lipid Profile and Glucose Measuring System should only be used with auto-disabling, single-use lancing devices.

The LipidPlus® Professional Glucose Test Strip is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

GENERAL

LipidPlus® Professional Glucose Test Strips use a new bio-sensor technology composed of electro-chemical components and require only a small volume of blood, resulting in less pain. The LipidPlus® Professional Lipid Profile and Glucose Measuring System can store 200 glucose test results in memory along with date and time of reading. You can also store your readings onto your PC (optional). This provides an easy and convenient way to control your glucose levels.

STORAGE AND HANDLING

- Store the LipidPlus® Professional glucose test strip vials in a cool, dry place between 36 ~ 86 °F (2 ~ 30 °C).
- Keep out of direct sunlight. Do not freeze.
- Store Glucose Test Strips in their original vial only. Do not mix the Glucose Test Strips in new vials or in any other container.
- Immediately replace the vial cap and close tightly after removing a LipidPlus® Professional Glucose Test Strip.
- Use glucose test strip immediately after removing it from the vial.
- Do not use Glucose Test Strips after the expiration date printed on the package or vial since it may cause inaccurate results.
- Make a notation of the discard date when you first open it. Discard any remaining Glucose Test Strips 3 months after first opening.
- Avoid getting dirt, food, and water on the glucose test strip. Do not handle Glucose Test Strips with wet hands.
- Do not bend, cut, or alter LipidPlus® Professional Glucose Test Strips.
- LipidPlus® Professional Glucose Test Strips are for single use only. Do not reuse.
- Do not perform tests at temperatures below 64°F (18°C) or above 86°F (30°C), at humidity below 10% or above 90%.
- Be careful not to dirty the auto-coding label. (Dirty color coding label due to dust and other substances)
- Discard the used glucose test strip carefully according to the local regulations.

Warning!
To avoid false readings, use only a LipidPlus® Professional Meter to measure glucose with your LipidPlus® Professional Glucose Test Strips.

CARE PROCEDURE

- Double check if the meter code matches the code number printed on the test strip vial
- Use only LipidPlus® Professional Glucose Test Strips with the LipidPlus® Professional Meter to obtain accurate and consistent results.
- Do not reuse Glucose Test Strips.
- The LipidPlus® Professional System can only be used for testing multiple patients when standard precautions and the manufacturer's disinfection procedures are followed.
- If your patient has experience any symptoms that are not consistent with the glucose test results and you have followed the instructions described in your LipidPlus® Professional instructions for Use, call Customer Service at 1-800-676-5565 or contact www.LipidPlus.com.

TEST PRINCIPLE

Glucose in the blood sample will react with the electrodes in the glucose test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the LipidPlus® Professional Meter and displayed as your patient's blood glucose result.

Note: The level of reaction with the electrode is dependent on the amount of glucose in the blood sample.

REAGENT COMPOSITION

Each LipidPlus® Professional Glucose Test Strip contains:
Glucose Oxidase (Aspergillusniger) :1 Units
Mediator (Hexaammineruthenium chloride) :60µg
Binder :1.9µg
Stabilizer :28.6µg

The procedure for Blood Glucose Measurement:
Materials provided: LipidPlus® Professional Glucose Test Strips

Obtaining Blood Sample:
The LipidPlus® Professional Glucose Test Strips are designed to be used with fresh capillary whole blood. The LipidPlus® Professional Meter gives you the ability to obtain a blood sample for testing your patient's glucose from different areas of the patient's body. You may obtain a drop of blood from either a fingertip or an alternative site.

CAUTION:
• LipidPlus® Professional Meter is for multi patient use.
• All parts of the kit are considered bio hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
• Please refer to the user's manual for cleaning and disinfecting LipidPlus® Professional system.
• Always use a new disposable lancing device. Disposable lancing devices are for single use only.
• Avoid getting hand lotions, oils, dirt or debris in or on the lancing device.

To obtain a drop of blood, follow these steps:
Step 1: Cleanliness: Clean your hands with soap and water, and dry well. Wear a new pair of gloves. Have your patient clean hands with soap and water, and dry well. You can also use alcoholic cotton to clean the patient's finger. Please wait until alcohol disappears completely. (Dirt, oil, lotion, or sweat may affect the test result).
Step 2: Lancing: Prepare the disposable single-use lancing device.

CAUTION : Only auto-disabling, single use lancing devices should be used with this device.

Step 3: Insert the test strip: Remove glucose test strip from the vial. Recap the vial immediately to prevent moisture from affecting the other strips. Insert the glucose test strip, into the port of the meter, with "3.3>>" logo facing up. The meter will automatically turn on and display the code number. The glucose test strip icon with a drop of blood will be flashing at the top of your screen. You are now ready for testing.
Prick the test site. Only a small drop of blood is necessary for accurate test results. Touch the top edge of your glucose test strip. The meter will countdown from 3 to 1 and a result will be displayed.

Note: Lancing the side of fingertip is less painful. Do not squeeze or milk the puncture site

Step 4: The meter will automatically store results in the memory, for later retrieval. Push the ejector button forward to discard the glucose test strip

Important Information About Using Alternate Site Testing:
• Alternate sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
• Do not use alternate sites when your patient's blood glucose is changing rapidly such as following a meal, after an insulin dose or during or after physical exercise.
• When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternate site samples.
• When your patient's blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood sugar) level sooner than a test with an alternate sites sample.
• Use alternate sites samples only for testing prior to or more than two hours after meal, insulin doses, or physical exercise.
• Testing performed within two hours after meals, insulin doses, or physical exercise or whenever your patients feel that their glucose levels may be changing rapidly should be done from the fingertip.
• Use fingertip testing whenever you are concerned about patient's hypoglycemia (insulin reactions) such as when driving a car, particularly if your patient suffers from hypoglycemic unawareness (lack of symptoms to indicate an insulin reaction), as forearm testing may fail to detect hypoglycemia.
• Under certain conditions, blood glucose test results obtained using samples taken from alternate sites may differ significantly from fingertip samples. Do not use alternate sites when your patient's blood glucose is changing rapidly such as following an insulin dose or associated with physical exercise.
• Alternate sites testing (AST) should not be used to calibrate Continuous Glucose Monitors (CGMs) and should not be used in insulin dose calculations.

TEST RESULTS

The results are displayed on the LipidPlus® Professional Meter as milligrams of glucose per deciliter of blood (mg/dL). The glucose test meter displays results between 20~600mg/dL.
If the test result is below 20mg/dL, "Lo" will appear on the LipidPlus® Professional meter display.
If the test result is above 600mg/dL, "Hi" will appear on the LipidPlus® Professional meter display. This indicates extremely high blood glucose (hyperglycemia).

IMPORTANT NOTE: Blood glucose levels can appear to be lower or higher after a meal, physical exercise or any other event that can alter blood glucose levels. Before using the LipidPlus® Professional Blood Glucose Test, wait two hours prior to, or after a meal or physical exercise.

Range of Expected Values
Expected blood glucose values for nondiabetic adults are as follows:
Before eating < 100 mg/dL
Two hours after meals < 140 mg/dL
Reference:
American Diabetes Association. Standards of Medical Care in Diabetes—2011. Diabetes Care 2011; 34 (Suppl.1) S11-S61

IMPORTANT NOTE: If your patient's blood glucose result is unusually low or high, repeat the test again with a new test strip. If the results are still inconsistent, please confirm your patient blood glucose by clinical equipment.

Quality Control (System Maintenance):
LipidPlus® Professional Glucose Control Solution is used with the LipidPlus® Professional Glucose Measuring System. This ensures that the meter and Glucose Test Strips are working properly and/or the test is being performed correctly for the measurement of glucose in your patient's blood. It is very important that you test with glucose control solution routinely to make sure your results are accurate.

For the measurement of glucose in your patient's blood, It is very important that you test with glucose control solution routinely to make sure your patient's results are accurate.

LipidPlus® Professional Glucose Control Solution test can only be used with the LipidPlus® Professional Meter and should be used during the following:
• When a new vial of Glucose Test Strips is opened.
• Any suspicion that the meter or Glucose Test Strips are not working properly.
• When your patient's blood glucose test results are not consistent with your patient's symptoms, or if you think they are not accurate.
• If you drop the glucose test meter.
• Use routinely to obtain accurate results.

When the glucose control solution is applied to the top edge of the glucose test strip, you should get results within the expected range printed on the label of the glucose test strip vial. If the glucose control solution test results fall outside the range, repeat the test. Results that fall outside the range may be caused by:
• Error in performing the test.
• Failure to shake the glucose control solution vial well enough (must shake vigorously).
• Failure to discard the first drop of glucose control solution.
• Expired or contaminated glucose control solution.
• Glucose Test Strip deterioration.
• Glucose Test Meter malfunctions
• Glucose Control Solution that is too warm or cold

IMPORTANT NOTE:
If the LipidPlus® Professional Glucose Control Solution test results repetitively fall outside the range printed on the vial, the LipidPlus® Professional Glucose Test System may not be functioning properly. DO NOT use the LipidPlus® Professional Glucose Measuring System to test your patient's blood until you get a glucose control solution test result that falls within the range. If you continue to have problems, contact Customer Service at 1-800-676-5565.

Limitations of System:
The LipidPlus® Professional Glucose Test Strips provide accurate results when the following constraints are observed:
• Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
• Use only the LipidPlus® Professional Glucose Test Strips with the LipidPlus® Professional Meter.
• Use fresh capillary whole blood only.
• Do not use neonate samples.
• The test strips are for single use only. Do not reuse.
• Dehydration may increase level of test results.
• Using Glucose Test Strips at an altitude above 10,000 feet will effect test results.

Physician - Please note the following interferences that may affect test results:
• Extremes in hematocrit may affect test results. LipidPlus® Professional Glucose Test Strip results can be used with hematocrit levels in the range of 30% to 55%. If the hematocrit range is out of the range (30%~55%), then the test results may be lower or higher than actual value.
• Interferences: Acetaminophen, Uric Acid, Ascorbic Acid (Vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations in may cause inaccurately high results.
• Lipemic samples; Cholesterol up to 500 mg/dL or triglycerides up to 3000 mg/dL do not significantly affect the results.values beyond these levels should be interpreted with caution.
• Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
• EDTA containing tube is recommended as an anticoagulant tube

Performance Characteristics:
The performance of the Glucose Test Strips has been evaluated in laboratory and in clinical tests.
Measurement Range: The measurement range for LipidPlus® Professional glucose testing is 20 to 600 mg/dL.

Accuracy:
The accuracy results obtained with the LipidPlus® Professional Lipid Profile and Glucose Measuring System were compared to glucose results obtained with the Hitachi Glucose Auto meter 747, a laboratory instrument. Glucose levels were measured on 150 patients at three different clinical centers.

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
27/27(100%)	27/27(100%)	27/27(100%)

System accuracy results for glucose concentration ≥ 75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/133(75%)	130/133(98%)	133/133(100%)	133/133(100%)

Alternate Site:
We alternate site glucose test results obtained from alternative sites were compared to the glucose results obtained with the Hitachi Glucose Auto meter 747(reference method), a laboratory instrument. Glucose levels were measured at three different clinical centers.

Test results for **DORSAL HAND** were compared to the reference method.

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5(80%)	5/5(100%)	5/5(100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
112/145(77%)	143/145(99%)	145/145(100%)	145/145(100%)

Test results of **VENTRAL HAND** were compared to the reference method.

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5(80%)	5/5(100%)	5/5(100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
111/145(77%)	143/145(99%)	145/145(100%)	145/145(100%)

Test results **UPPER ARM** were compared to the reference method.

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5(80%)	5/5(100%)	5/5(100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
109/145(75%)	143/145(99%)	145/145(100%)	145/145(100%)

Test results **FOREARM** were compared to the reference method.

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5(80%)	5/5(100%)	5/5(100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
95/145(66%)	137/145(94%)	143/145(99%)	145/145(100%)

Test results **THIGH** were compared to the reference method.

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
3/5(60%)	5/5(100%)	5/5(100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
103/145(71%)	137/145(94%)	144/145(99%)	145/145(100%)

Test results **CALF** were compared to the reference method.

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
2/5(40%)	5/5(100%)	5/5(100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/145(69%)	138/145(95%)	145/145(100%)	145/145 (100%)

Precision: Repeatability evaluation for venous blood samples.					
Mean (mg/dL)	45.0	84.7	130.8	206.2	341.8
CV (%)	3.1	2.1	2.2	2.6	2.4

Intermediate evaluation for control solutions.			
Mean (mg/dL)	49.7	100.5	300.3
CV (%)	2.3	1.7	0.7

IMPORTANT
• Before using the LipidPlus® Professional Meter and Glucose Test Strips, read Meter Operating Manual and Instructions for Use.
• If you have any questions regarding use of the products, please contact customer service at 1-800-676-5565 or go to www.LipidPlus.com.

OUR COMMITMENT TO YOU:
We understand that lipid profile levels provide a way to control hyperlipidemia and cardiovascular disease. As a result, the LipidPlus® Professional Lipid Profile and Glucose Measuring System were developed to help manage hyperlipidemia and cardiovascular disease by the most comfortable and convenient way possible. Our goal at Jant Pharmacal Corporation is to provide you with quality products and superior customer service. If you have any questions or comments, please contact info@lipidplus.com or visit our website at www.LipidPlus.com.

Customer Service is available Monday through Friday, from 7:30AM to 5:00 PM Pacific Time. Please Call Customer Service toll Free : 1-800-676-5565.

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